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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/750,022	12/29/2000	Indu J. Isaacs	016777/0454	6419

7590 03/08/2002
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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 03/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/750,022

Applicant(s)

ISAACS, INDU J.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Applicants claim foreign priority, however, the priority document (United Kingdom 993-882.7) has not been submitted. Therefore, the priority date is not perfected.

Election/Restrictions

2. Applicant's election with traverse of Group II, claims 49-54 along with the product claims 1-35 and 43-48 in Paper No. 6 is acknowledged. Applicants traverse on the ground(s) that claims 36-42 of Group I can be examined with Group II without serious search burden. The argument is found persuasive. Upon reconsideration, Group I is rejoined with Group II. Thus, claims 1-54 are examined.

Claim Objections

3. Claim 14 is objected to because of the use of the term "n animal". Appropriate correction is required.

4. Bracketing or underlining are commonly used to indicate amendments or changes in the claims as provided in 37 CFR 1.121(a)(2)(ii) and are normally not intended to be printed in the published patent. For example, in claims 15 and 32, applicant has used "h[Gly2]GLP-2" in such a manner that appears that the instant brackets would indicate deleted material and is thus, confusing as to whether the h[Gly2]GLP-2 in claims 15 and 32 would include "Gly2" or not.

The applicant can only amend by cancellation and presentation of a new claim. See also changes to 37 CFR 1.121 in Amendment rules package (Final Rule published on 8 Sep. 2000 (65 Fed. Reg. 54603), see also O. G. of 19 Sep. 2000 (1238 Off. Gaz. Pat. Office 77)).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-54 are indefinite because of the use of the term "GLP-2". The term "GLP-2" renders the claim indefinite, it is not clear what the term means. A full spelled out word should precede the term at the first occurrence. Claims 2-30, 32-35, 37-42, 44-48 and 50-54 are included in this rejection for being dependent on rejected claims and not correcting the deficiency of the claims from which they depend.

6. Claims 1-14, 17 and 22-54 are indefinite because of the use of the term "an analog". The term "an analog" renders the claim indefinite, it is unclear what amino acid sequence the analog has as compared to the parent peptide. Claims 2-14, 17, 22-30, 32-35, 37-42, 44-48 and 50-54 are included in this rejection for being dependent on rejected claims and not correcting the deficiency of the claims from which they depend.

7. Claims 2 and 3, for example, are indefinite because of the use of the term "greater than about 6.0" or "from about 6.9 to about 7.9". The term "greater than about 6.0" or "from about 6.9 to about 7.9" renders the claim indefinite, it is unclear the pH of the formulation is greater or less than pH 6.0, and the pH is in the range of pH 6.9 to 7.9 or outside the range. Deletion of the term "about" is suggested. See also claims 4, 34, 35, 37-41, 44, 45, 50 and 51.

8. Claims 23 and 25, for example, are indefinite because of the use of the term "less than about 5%", "for up to at least 6 months" or "less than about 3 to about 4%". The term "less than about 5%", "for up to at least 6 months" or "less than about 3 to about 4%" renders the claim

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indefinite, it is unclear the water content in the lyophilized formulation is greater or less than 5%, how many months the GLP-2 formulation is being stable, and the percentage of degradation of GLP-2 is in the range of 3 to 4% or outside the range. See also claims 26-30, 41 and 47.

9. Claim 17 is indefinite because of the use of the term "one or more amino acid substitutions, additions, deletions or modifications" or "biological activity". The term "one or more amino acid substitutions, additions, deletions or modifications" or "biological activity" renders the claim indefinite, it is unclear how many and which amino acids are modified, and what amino acids are used for modifications, and what the biological activity is because the biological activity is not specified in the claim.

10. Claim 48 is indefinite because of the use of the term "up to about 24 hours". The term "up to about 24 hours" renders the claim indefinite, it is unclear the GLP-2 formulation is stable less than or more than 24 hours.

11. Claim 49-54 are indefinite because of the use of the term "a disorder, disease or condition" or "gastrointestinal disease". The term "a disorder, disease or condition" or "gastrointestinal disease" renders the claim indefinite, it is unclear what disease a human or animal has. Claims 50-54 are included in this rejection for being dependent on rejected claims and not correcting the deficiency of the claims from which they depend.

12. Claims 49-54 are indefinite because the claims lack essential steps in the method of treating a human or an animal having a disease using the GLP-2 formulation. The omitted steps are: the method of administration, the effective amount of formulation and the outcome for the treatment. Claims 50-54 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

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Conclusion

13. No claims are allowed.

Art of Record

Knudsen *et al.* (WO 99/43361) teach a pharmaceutical composition comprising a GLP-2 derivative or analog, an isotonic agent such as mannitol, a buffer of histidine or sodium phosphate, a pharmaceutical acceptable carrier, a preservative and a surfactant, where the solubility and stability of GLP-2 is improved (page 4, line 19-29; page 3, lines 24-25). The reference also indicates the concentration of the GLP-2 derivative is more than 0.5 mg and less than 100 mg/ml (page 4, lines 9-12; page 13, lines 16-19), the formulation can be obtained in lyophilized form (page 13, line 10), and the pharmaceutical composition can be administered by injection or means of infusion pump to treat small bowel^e syndrome or intestinal inflammation (page 12, lines 13-16; page 13, 16-24, for claims 49-54). However, Knudsen *et al.* does not disclose using histidine as a stabilizing agent. Makino *et al.* (U. S. Patent 4,985,244) disclose using histidine as a stabilizing agent in a vaccine composition (column 1, lines 15-20), however, it is not known whether histidine can stabilize GLP-2 or its analogs in the GLP-2 formulation. Thus, the references do not teach the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

Karen Cochrane Carlson
KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

March 3, 2002